

1: N Engl J Med 1992 Dec 3;327(23):1637-42

Vitamin D3 and calcium to prevent hip fractures in the elderly women.

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**BACKGROUND.** Hypovitaminosis D and a low calcium intake contribute to increased parathyroid function in elderly persons. Calcium and vitamin D supplements reduce this secondary hyperparathyroidism, but whether such supplements reduce the risk of hip fractures among elderly people is not known. **METHODS.** We studied the effects of supplementation with vitamin D3 (cholecalciferol) and calcium on the frequency of hip fractures and other nonvertebral fractures, identified radiologically, in 3270 healthy ambulatory women (mean  $\pm$  SD age, 84  $\pm$  6 years). Each day for 18 months, 1634 women received tricalcium phosphate (containing 1.2 g of elemental calcium) and 20 micrograms (800 IU) of vitamin D3, and 1636 women received a double placebo. We measured serial serum parathyroid hormone and 25-hydroxyvitamin D (25(OH)D) concentrations in 142 women and determined the femoral bone mineral density at base line and after 18 months in 56 women. **RESULTS.** Among the women who completed the 18-month study, the number of hip fractures was 43 percent lower ( $P = 0.043$ ) and the total number of nonvertebral fractures was 32 percent lower ( $P = 0.015$ ) among the women treated with vitamin D3 and calcium than among those who received placebo. The results of analyses according to active treatment and according to intention to treat were similar. In the vitamin D3-calcium group, the mean serum parathyroid hormone concentration had decreased by 44 percent from the base-line value at 18 months ( $P < 0.001$ ) and the serum 25(OH)D concentration had increased by 162 percent over the base-line value ( $P < 0.001$ ). The bone density of the proximal femur increased 2.7 percent in the vitamin D3-calcium group and decreased 4.6 percent in the placebo group ( $P < 0.001$ ). **CONCLUSIONS.** Supplementation with vitamin D3 and calcium reduces the risk of hip fractures and other nonvertebral fractures among elderly women.

Publication Types:

Clinical Trial

Controlled Clinical Trial

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Evaluation of a new solid formulation of calcium and vitamin D in institutionalized elderly subjects. A randomized comparative trial versus separate administration of both constituents.

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Supplementation with 800 IU of vitamin D and 1 g of calcium each day is recommended in institutionalized elderly subjects to prevent secondary hyperparathyroidism and its adverse skeletal effects. An original formulation (IDEOS) combining vitamin D and calcium has been developed for use in this end. The aim of this study was to determine whether administration of this association, of which each tablet contains 500 mg calcium and 400 IU vitamin D3, produces the same beneficial effects on laboratory parameters as separate administration of both active agents. A multicenter randomized study was conducted in 91 elderly institutionalized subjects (mean age 83.1 years) who had vitamin D deficiency [ $25\text{-(OH)D} < 6 \text{ ng/ml}$ ] without severe renal failure. Subjects were randomly assigned to one of the two treatment groups. Treatment duration was six months. One group (G1,  $n = 46$ ) received one tablet of the new formulation twice daily. The other (G2,  $n = 45$ ) received 8 drops of vitamin D3 (800 IU/day) and one calcium carbonate 500 mg tablet twice daily. Blood tests were carried out at inclusion and after three and six months of treatment. In group G1, plasma  $25\text{-(OH)D}$  levels increased from 2.6 ng/ml at inclusion to 14.6 ng/ml at month 6 ( $p < 0.001$ ), and iPTH fell from 63.2 pg/ml at inclusion to 33.8 pg/ml at month 6 ( $p < 0.001$ ). In group G2,  $25\text{-(OH)D}$  rose from 2.8 ng/ml at inclusion to 13.5 ng/ml at month 6 ( $p < 0.001$ ), and iPTH fell from 55.4 pg/ml at inclusion to 32.5 pg/ml at month 6 ( $p < 0.001$ ). (ABSTRACT TRUNCATED AT 250 WORDS)

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Publication Types:

Clinical Trial

Multicenter Study

Randomized Controlled Trial

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